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499-625—73——1

CITATIONS

In the Supreme Court of the United States

OCTOBER TERM, 1972

No. 72-528

CIBA CORPORATION, PETITIONER

v.

CASPAR W. WEINBERGER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND DR. CHARLES C. EDWARDS, COMMISSIONER OF FOOD AND DRUGS

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE RESPONDENTS

OPINIONS BELOW

The opinion of the court of appeals (A. 215) is reported at 463 F. 2d 225. The order of the district court (A. 214) is not reported. The district court did not enter a written opinion.

JURISDICTION

The judgment of the court of appeals (A. 216) was entered on June 5, 1972. By order dated September 1, 1972, Mr. Justice Rehnquist extended the time for filing a petition for a writ of certiorari to October 2, 1972. The petition was filed on that date and was

granted on January 8, 1973 (A. 217).[1] The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTES INVOLVED

Relevant provisions of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040, as amended, 21 U.S.C. 301 *et seq.*, are set forth in the appendix (A. 475–481).

QUESTION PRESENTED

Whether a manufacturer is entitled to litigate *de novo* in district court the status of his product as a "new drug" when FDA has withdrawn approval of the product's new drug application for failure to establish the product's effectiveness, and the agency determination has been upheld on direct judicial review.

STATEMENT

Petitioner Ciba Corporation ("Ciba") manufactures a drug product, Ritonic Capsules,[2] for which it filed a

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[1] On the same day this Court granted writs of certiorari in four related cases, consolidated them with this one, and allotted a total of three hours of argument. The four other cases are *Weinberger* v. *Hynson, Westcott and Dunning, Incorporated*, No. 72–394; *Hynson, Westcott and Dunning, Incorporated* v. *Weinberger*, No. 72–414; *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, No. 72–555; and *USV Pharmaceutical Corporation* v. *Weinberger*, No. 72–666.

[2] "Ritonic Capsules" is a combination of a stimulant (methylphenidate hydrochloride), vitamins and hormones (A. 197). It is a prescription drug recommended "for patients who are losing their drive, alertness, vitality and zest for living because of the natural degenerative changes of advancing years"; and for patients who are "debilitated or depressed by chronic illness, overwork, etc., as well as those recuperating from illness or surgery" (A. 198).

new drug application ("NDA") that became effective in 1959. At that time, the Federal Food, Drug, and Cosmetic Act of 1938 defined a "new drug," in pertinent part, as a drug not generally recognized by qualified experts as safe for its intended uses (Section 201(p)(1), 21 U.S.C. (1958 ed.) 321(p)(1))[3] and provided that such a drug could not be marketed unless an NDA were in effect for it (Section 505(a), 21 U.S.C. (1958 ed.) 355(a)). Under that Act, an NDA for a "new drug" was to become effective if its manufacturer submitted to the Food and Drug Administration ("FDA")[4] with its application adequate proof of the drug's safety (Section 505(b), (c), and (d), 21 U.S.C. (1958 ed.) 355(b), (c), and (d)).[5] The NDA for Ritonic Capsules was permitted to become effective on the basis of the drug's safety.

The 1962 Amendments to the Federal Food, Drug, and Cosmetic Act, among other things, direct the Secretary to withdraw approval for NDAs permitted to

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[3] Relevant provisions of the Federal Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. (1958 ed.) 301 *et seq.*) are set forth at A. 482–484. In order to avoid "new drug" status, a product must also have "been used to a material extent or for a material time" (Section 201(p)(2), A. 483). This portion of the definition is not involved in the issues presented by the instant case.

[4] The Commissioner of Food and Drugs administers the Act pursuant to a delegation of authority by the Secretary of the Department of Health, Education, and Welfare. See our brief in *Weinberger* v. *Bentex Pharmaceutical, Inc.*, No. 72–555, p. 4, n. 5 (hereinafter "Pet. Br. *Bentex*").

[5] The Federal Food, Drug, and Cosmetic Act of 1938, prior to its amendment in 1962, is described more fully in Pet. Br. *Bentex*, pp. 3–5.

become effective prior to 1962, if, after notice and opportunity for hearing, he finds a lack of "substantial evidence" that the drug involved is effective as claimed in its labeling. The statute defines "substantial evidence" to mean "adequate and well-controlled investigations" from which experts could conclude that the drug will have the effect claimed for it. Sections 505 (d) and 505(e)(3), 21 U.S.C. 355(d) and 355(e)(3) (A. 478–479).[6]

1. *The agency proceedings.* Pursuant to FDA's program for implementing the 1962 Amendments,[7] the panel on psychiatric drugs established by the National Academy of Sciences—National Research Council ("NAS–NRC") reviewed the claims made for Ritonic Capsules and found it "ineffective" for each of its claimed indications (A. 196–197). The Commissioner, after review of the NAS–NRC evaluation, also concluded that there was a lack of substantial evidence of Ritonic Capsules' efficacy and accordingly, on September 12, 1969, issued a notice announcing his intention to withdraw its NDA. The notice offered Ciba an opportunity to submit adequate and well-controlled studies bearing on the efficacy of the drug and also stated that withdrawal of approval for the NDA would cause Ritonic Capsules to be a "new drug" for which no NDA is in effect (A. 199–202), thereby making future sale of the drug unlawful.

Ciba responded to the notice by letter dated October 10, 1969 (A. 202–203). It disputed the Commis-

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[6] See Pet. Br. *Bentex*, pp. 14–15.

[7] See *id.*, pp. 16–19.

sioner's conclusion that there was a lack of substantial evidence of Ritonic Capsules' efficacy; submitted "by incorporation by reference" data it had previously submitted to FDA; and reserved "all rights to assert that Ritonic is not a new drug and is not subject to the provisions of Section 505 of the Food, Drug, and Cosmetic Act as amended (21 U.S.C. 355)."

On August 5, 1970, having concluded that the information submitted by Ciba did not provide substantial evidence of the drug's effectiveness, the Commissioner published a notice of opportunity for a hearing on his proposal to withdraw approval for Ritonic Capsules' NDA (A. 203–206). In accordance with the statute and the applicable regulations (21 C.F.R. 130.12(a)(5), 130.14) (A. 487–491),[8] the Commissioner conditioned the hearing on the proffer by Ciba of "a well-organized and full-factual analysis of the clinical and other investigational data [it is] prepared to prove in support of [its] opposition" to the proposed withdrawal (A. 205). Once again the Commissioner announced that withdrawal of approval for Ritonic Capsules' NDA would cause any drug containing the same components with the same claimed uses "to be a new drug for which an approved new-drug application is not in effect" (A. 204) and which therefore could not be marketed lawfully.

By letter dated August 31, 1970, Ciba responded to the notice of opportunity for hearing (A. 206–207). It "elect[ed] to avail itself of the opportunity for a hearing"; contested the Commissioner's authority to

[8] See Pet. Br. *Bentex*, p. 22.

require a statement as to why approval should not be withdrawn as a condition for a hearing; and advised the Commissioner of Ciba's "position that Ritonic Capsules are not now a new drug under the [Act] and that the amendments of 1962 are not applicable to that drug." Ciba's decision to request a hearing, it said, "is made with a reservation of the right to establish these facts in the administrative proceedings, or in judicial proceedings, or both."

Ciba did not file any data to support its request for a hearing or state reasons why approval for its NDA should not be withdrawn. Accordingly, on September 30, 1970, the Commissioner published an order withdrawing approval for Ritonic Capsules' NDA on the ground that there is a lack of substantial evidence that the drug is effective as claimed (A. 207–208).

Ciba petitioned for review of the withdrawal order in the Second Circuit pursuant to Section 505(h) of the Act.[9] On July 16, 1971, the Second Circuit affirmed the withdrawal order, upholding the requirement imposed by the agency's regulations that in a proceeding to withdraw approval for an NDA for lack of "substantial evidence" of effectiveness, the applicant must

[9] Section 505(h), 21 U.S.C. 355 (h), A. 480–481, provides in pertinent part: "An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside."

demonstrate that it has such evidence in order to obtain a full evidentiary hearing. *Ciba-Geigy Corp.* v. *Richardson,* 446 F. 2d 466. Ciba did not seek review in this Court of the Second Circuit's decision.

2. *Proceedings below.* Meanwhile, on September 4, 1970, prior to the issuance of the withdrawal order, Ciba commenced this suit for declaratory and injunctive relief in the federal district court in New Jersey (A. 185–192). It alleged that Ritonic Capsules is not subject to the efficacy requirements of the amended Act by virtue of the exemption provision in Section 107 (c)(4) of the 1962 Amendments,[10] and alternatively that Ritonic Capsules is not now a "new drug" under the amended definition of that term contained in Section 201(p)(1) of the Act (21 U.S.C. 321(p)(1), A. 475) because it is now "generally recognized [by qualified experts] as safe and effective" for its claimed uses (A. 191–192). Ciba asserted that the administrative hearing on the proposal to withdraw approval for Ritonic Capsules' NDA would not encompass those issues, "because the FDA lacks the power to adjudicate [those] issue[s]," but would involve only a resolution of the question whether there is "substantial evidence" of Ritonic Capsules' effectiveness (A. 190, 192). Ciba therefore alleged that it had "exhausted all administrative avenues by which it may seek a determination of its rights on [those] issue[s]" (*ibid.*).

On January 11, 1971, after hearing argument, the district court granted the government's motion to dis-

[10] P.L. 87–781, Section 107(c)(4), 76 Stat. 789, note following 21 U.S.C. (1970 ed.) 321 (A. 482).

miss the complaint for lack of jurisdiction (A. 214). At that time, Ciba's petition to review the order withdrawing approval for its NDA was pending in the Second Circuit. The district court ruled that it did not have jurisdiction to entertain the action under the Declaratory Judgment Act, but that, assuming it did have jurisdiction, it would nevertheless exercise its discretion to dismiss the complaint (*ibid.*).

On appeal, the Third Circuit affirmed, *per curiam* (A. 215–216). In its appeal, Ciba contended that neither the FDA in the withdrawal proceeding nor the court of appeals on direct review of the agency's action had jurisdiction to decide the question whether the product involved is a "new drug" which requires an NDA for lawful marketing. Rather, Ciba argued, the district courts have exclusive jurisdiction to decide that issue, and Ciba was entitled to litigate it in the district court.

The Third Circuit rejected that argument, holding that the agency necessarily is empowered to decide the jurisdictional question as an incident of its power to approve or withdraw approval for NDAs, and that its decision on that issue is reviewable in the court of appeals on direct review of the agency's order. Since the jurisdictional issue was implicitly decided adversely to Ciba by the FDA and the Second Circuit on direct review of FDA's withdrawal order, the Third Circuit concluded that Ciba was not entitled to litigate that question in a separate suit for a declaratory judgment (A. 216).

SUMMARY OF ARGUMENT

This case presents the same basic issue, although in a different context, as *Weinberger* v. *Bentex Pharmaceuticals, Inc.,* No. 72–555: Whether the FDA has jurisdiction in an administrative proceeding to determine whether a drug product is a "new drug" under the definition in Section 201(p) of the Act. The reasons why the FDA has that authority are developed in the government's brief in *Bentex,* and we shall only summarize them in this brief.

This case dramatically illustrates the fallacy of the Fourth Circuit's holding in *Bentex* that the FDA never has jurisdiction to determine the question whether a drug product is a "new drug" under the definition in Section 201(p) of the Act, even in conjunction with the exercise of its regulatory responsibilities under Section 505. Under the *Bentex* holding and the arguments advanced by petitioner in the instant case, the agency must go forward with its regulatory proceedings and the court of appeals with judicial review thereof, while the drug manufacturer retains the right to attempt to establish in *de novo* judicial proceedings that the agency was, after all, simply engaging in an exercise in futility, because the product was not subject to its regulatory powers in the first place.

Such a view is inconsistent with the fundamental scheme established by Congress to regulate the safety and effectiveness of drugs used by the American public, under which administrative regulation will be the primary safeguard, to be supplemented by judicial

enforcement proceedings as a second line of defense. Petitioner's approach would thrust upon the district courts the principal burden of dealing with the complex medical and pharmacological questions underlying the determination of "new drug" status and would entail an extremely wasteful, duplicative approach to drug regulation.

As the court of appeals correctly concluded, FDA's institution of the NDA withdrawal proceeding was itself an assertion that Ritonic Capsules is subject to the Act, and the jurisdictional question was inherent in the proceeding. Petitioner should have contested the "new drug" status of its product before the agency, and, if it believed that the agency applied an incorrect standard in determining that the product was a "new drug" within its regulatory jurisdiction, petitioner should have sought review of that aspect of the agency's determination in its direct appeal to the Second Circuit. Having failed to do so, the finding of "new drug" status became *res judicata* as to petitioner and precludes relitigation in an independent judicial proceeding.

Even if that were not so, petitioner could not prevail in its district court action, since it is undisputed that FDA had the power to determine and did determine that there was a lack of substantial evidence of the effectiveness of Ritonic Capsules. Since, as we argue in our brief in No. 72–414 (the cross-petition in the *Hynson* case), a drug could not be generally recognized as effective if FDA has found that there is a lack of substantial evidence of effectiveness, FDA's

finding to this effect in the administrative proceeding was binding on petitioner and under principles of collateral estoppel precludes it from arguing that its product is not a "new drug."

ARGUMENT

CIBA IS NOT ENTITLED TO A DE NOVO JUDICIAL DETERMINATION OF ITS PRODUCT'S "NEW DRUG" STATUS

Ciba claims entitlement to *de novo* consideration by the district court of Ritonic's "new drug" status on the theory that the issue presented is one beyond the power of FDA to determine administratively, so that the NDA withdrawal proceeding and the subsequent direct judicial review thereof would not have foreclosed new litigation of the "new drug" question.[11] The underlying issue in this case is thus whether FDA ever has authority to determine administratively whether a product is a "new drug" requiring an approved NDA for lawful marketing.

The same issue is presented in *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, No. 72–555,[12] in which the

[11] Even if Ciba were correct in its jurisdictional argument, however, the district court rightly dismissed its declaratory judgment action. As we indicate at pp. 18–20, *infra*, and discuss at greater length in our brief in No. 72–414, the finding that Ritonic fails to satisfy the effectiveness requirements of Section 505 precludes a finding of "not new drug" status under Section 201(p). Ciba's action therefore must fail under the doctrine of collateral estoppel.

[12] This issue is presented by cross-petitioner Hynson, Westcott and Dunning in No. 72–414. It has aligned itself with the government on this question, arguing that FDA has the authority to determine whether the drug involved in that case requires an NDA for lawful marketing (Brief for Cross-Petitioner in No. 72–414, pp. 17–20).

Fourth Circuit ruled that the FDA may never make that jurisdictional determination administratively. In our brief in *Bentex*, we have shown that the decision denying to FDA the power to determine in its own proceedings the coverage of the Act it administers is inconsistent with the scheme of the Act and would seriously impair FDA's ability to carry out its congressionally assigned responsibility to remove from the market drugs not shown to be effective (Pet. Br. *Bentex*, pp. 34–38, 40–47). The brief also shows why the premises upon which the Fourth Circuit based its *Bentex* decision are erroneous (*id.* at 47–57).

Petitioner Ciba advances essentially the same arguments, to support its contention that the district court is the sole forum in which the "new drug" status of its product may be litigated, as those relied on by the Fourth Circuit in *Bentex*. Since the Court already has before it our argument on these issues, as presented in our brief in *Bentex*, we shall simply summarize them briefly here.

1. *FDA's authority to determine the coverage of the Act is implicit in the statutory scheme.* The Act confers broad administrative responsibilities on the FDA to protect the public by screening all "new drugs" for safety and effectiveness prior to marketing and by maintaining a continuous review of "new drugs" on the market to assure that the agency's initial determination respecting safety and effectiveness conforms to developing medical knowledge and experience. Section 505, 21 U.S.C. 355, A. 477–480. In addition to the administrative responsibility to approve or withdraw

approval for the marketing of new drugs expressly conferred by Section 505, the Act empowers FDA to promulgate regulations (Section 701(a), 21 U.S.C. 371(a)) and conduct investigations (Section 702(a), 21 U.S.C. 372(a)) to carry out the purposes of the Act. The exercise by FDA of these regulatory functions serves as the primary public safeguard against the marketing of unsafe and ineffective drugs. Implicit in the grant of these broad regulatory powers is the power to decide the question on which the FDA's regulatory responsibility turns: Whether the product involved is a "new drug" for which approval is necessary under Section 505.

Section 201(p)(1) defines "new drug" as "[a]ny drug * * * the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof * * *." This definition suggests a determination of technical and scientific questions by experts. It requires a consideration and disposition of issues substantially similar to the isues involved in an agency proceeding for approval or withdrawal of approval of an NDA under Section 505 (see Pet. Br. *Bentex,* pp. 55–57). Resolution of the question of the agency's jurisdiction, which turns on a proper assessment of technical and scientific factual considerations, is therefore a function for which the agency is particularly well-suited.

Thus, the absence of an express grant of power authorizing the agency to determine the coverage of the Act it administers, upon which Ciba (Br. 8) and the *Bentex* opinion (see A. 266) rely, is not dispositive. Just as "[a]uthority to investigate the existence of violations * * * include[s] authority to investigate coverage" (*Oklahoma Press Pub. Co.* v. *Walling*, 327 U.S. 186, 210–211, n. 47), authority to grant, refuse, or withdraw marketing approval necessarily includes authority to determine the threshold question of coverage—whether the product involved is a "new drug" which requires agency approval. See Pet. Br. *Bentex*, pp. 57–60. Indeed, agencies routinely determine the coverage of the statutes they administer, even though the statutes themselves rarely confer explicit authority to do so.

2. *The district court's jurisdiction under the enforcement provisions of the Act does not bar FDA from determining the coverage of the Act.* The Act prohibits, among other things, the sale in commerce of any article in violation of Section 505's requirement of an NDA approved by the agency after administrative consideration. Section 301(d), 21 U.S.C. 331(d), A. 475. It prescribes civil injunction proceedings, criminal penalties, and *in rem* seizure and condemnation to give effect to this and other prohibitions. Sections 302(a), 303, 304, A. 475–477. These judicial enforcement provisions constitute a second line of defense backing up the administrative system of marketing approval established by the Act. They are designed to complement, rather than displace, the administrative approval scheme.

Petitioner's construction of the Act, which provides for mutually exclusive forums for regulating new drugs—one judicial, the other administrative—is both unnecessary and impractical. That the district courts may determine *de novo* in enforcement proceedings whether a product is a "new drug," at least where there has been no formal administrative determination of that issue, does not mean that the agency is therefore powerless to determine its own jurisdiction in the proceedings it conducts.

The impractical consequences of the dual system of regulation urged by petitioner are apparent. It would make the district courts, rather than the agency, the principal forum for determining in all instances whether a product is a "new drug" subject to the administrative clearance and review provisions of Section 505 of the Act. It would thus transfer to the district courts sole responsibility to resolve the often complex questions upon which the definition of "new drug" turns—questions which the expert agency is inherently well suited to resolve.[13]

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[13] Petitioner asserts (Br. 10) that resolution of the question whether a product is a "new drug" (*i.e.*, whether it is generally recognized by experts as safe and effective) involves only a determination of the consensus among doctors, which is "readily within the competence of the courts." In the district court, however, petitioner asserted that a determination of the "new drug" question would involve the testimony of "many experts," and "a great factual investigation and presentation [to the] trier of the facts * * *" (A. 211). This submission reinforces our position that it is the agency in the first instance which should resolve such factual questions peculiarly within its competence.

The necessity for a two-step procedure—an agency proceeding to determine whether NDA approval should be withdrawn and a judicial proceeding to determine whether the NDA was after all required—would inordinately protract FDA's efforts to remove from the market drugs not shown to be effective. Both questions can be and should be decided in a single proceeding. Familiar principles require manufacturers in petitioner's position to raise their objections to the agency's proceeding during that proceeding, instead of "reserving" those objections for *de novo* judicial consideration. See *Myers* v. *Bethlehem Corp.*, 303 U.S. 41.

Petitioner suggests (Br. 11–12) that the agency's failure to raise in the administrative withdrawal proceedings the question whether Ritonic Capsules is a "new drug" shows that petitioner was foreclosed from presenting that issue to the agency for resolution. On the contrary, as the court below observed (A. 216), the institution of the withdrawal proceedings was itself an assertion that Ritonic Capsules is subject to the Act, and the jurisdictional question was therefore inherent in that proceeding. Indeed, petitioner's careful attempt to "reserve" the jurisdictional issue (A. 203, 206–207) (*i.e.*, withhold it from the agency) indicates that petitioner was of a similar view.[14]

[14] The absence of formal agency regulations setting forth the manner in which jurisdictional questions may be raised did not preclude petitioner from raising the issue. Nor does it indicate that the agency considers itself powerless to determine its own jurisdiction. If petitioner had serious doubts as to whether the agency would entertain petitioner's jurisdictional claims, it should have raised the question before the agency, rather than attempting to reserve it.

Even were petitioner justified in supposing that the agency would have refused to consider its "new drug" contentions—contentions that FDA deems insupportable in the absence of "substantial evidence" of drug effectiveness—its proper remedy was to challenge the correctness of FDA's approach on direct judicial review.[15] Having failed to do so, Ciba is not free to relitigate it in an independent proceeding. See cases cited at note 17, *infra*; cf. *Marine Terminal Assn.* v. *Rederi. Transatlantic*, 400 U.S. 62, 72.

3. *Judicial review of the agency's "new drug" determination is available.* Section 505(h) of the Act (21 U.S.C. 355(h), A. 480–481) provides for direct review in the courts of appeals of an agency order denying or withdrawing approval for an NDA, and petitioner invoked that provision to obtain review in the Second Circuit of the order withdrawing approval for Ritonic Capsules' NDA. In urging that Section 505(h) precludes a court of appeals from reviewing an agency finding that a product is a "new drug," we believe petitioner misreads the statute. Section 505(h) authorizes appeals from certain kinds of orders; it does not, as petitioner suggests (Br. 9), confer jurisdiction on the courts of appeals in terms of particular issues.

The only limitation imposed by Section 505(h) on the issues a court of appeals may decide on direct review is that the issue must have been raised before the agency: "No objection to the order of the Secretary

[15] This was the course followed by Hynson, Westcott & Dunning, which now has before this Court the issue of the correctness of FDA's disposition of its "not new drug" contentions in No. 72-414.

shall be considered by the court [of appeals] unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do." [16]

4. *Petitioner's suit for declaratory relief was properly dismissed.* Petitioner had the opportunity to litigate the "new drug" issue in the administrative proceeding to which it was a party and in which it participated, and it also had the right to judicial review in the court of appeals of the adverse agency determination of that issue. Its failure to raise that issue, indeed its affirmative attempt to carve it out of the administrative proceeding, precludes petitioner from litigating the "new drug" issue in another proceeding, whether it is a declaratory judgment action or an enforcement suit.[17]

5. *Even if petitioner were correct in its jurisdictional argument, it would be barred from relief by collateral estoppel.* It is not disputed that FDA had jurisdiction to consider, and did consider and pass upon, the question whether "there is a lack of substantial evidence that [Ritonic Capsules] will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof," the standard for with-

[16] Where, as in *Bentex*, the agency's "new drug" determination is not reviewable in the courts of appeals pursuant to Section 505(h), it is reviewable in the district courts under the Administrative Procedure Act. See, Pet. Br. *Bentex*, pp. 51-53.

[17] See, *e.g.*, *United States* v. *Ruzicka*, 329 U.S. 287; *Yakus* v. *United States*, 321 U.S. 414, 444-446; cf. *McGee* v. *United States*, 402 U.S. 479.

drawal of approval set forth in Section 505(e)(3). The agency found that there is a lack of substantial evidence of effectiveness, and this finding was affirmed by the Second Circuit. The doctrine of collateral estoppel bars petitioner from relitigating the question in another proceeding.

It is the government's position that a drug that has been determined not to meet either the safety or the effectiveness standards of Section 505 is thereby *a fortiori* a "new drug" under Section 201(p). This is so because, in the absence of scientifically acceptable evidence of safety or effectiveness of the quality and quantity prescribed by Congress for approval of new drug applications, the "experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs," on whose judgment the application of the "new drug" definition expressly depends, could not recognize the drug's safety and effectiveness. Any contrary position would lead to an anomalous situation in which the Act would leave drugs that the expert administrative agency had determined to be unsafe or ineffective unregulated because of judgments based on criteria for evaluation which Congress has expressly rejected.

If the Court agrees with our position, set forth at greater length in our brief in No. 72-414, that a drug must, at a minimum, be able to satisfy the safety and effectiveness criteria of Section 505 in order to attain "not new drug" status under Section 201(p), the conclusion of FDA in the withdrawal proceedings that there is a lack of substantial evidence of Ritonic

Capsules' effectiveness, which is binding on Ci through collateral estoppel, precludes relief to Ci in the declaratory judgment proceeding. See *Unite States* v. *Utah Constr. Co.*, 384 U.S. 394, 422; *Mari Terminal Assn.* v. *Rederi Transatlantic, supra*, 400 U. at 72; *Restatement of Judgments* §§ 68, 69 (1942).

CONCLUSION

For the foregoing reasons and the reasons advanced in our brief in *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, No. 72–555, the judgment of the court o appeals should be affirmed.

Respectfully submitted.

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APRIL 1973.

U.S. GOVERNMENT PRINTING OFFICE: 1973